

Exhibit A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 94247; 58898/130

In re patent application of

David J. BOVA

Group Art Unit: 1502

Serial No.: 08/368,378

Examiner: J. Venkat

Filed: June 14, 1995

For: NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA
AND RELATED METHODS THEREOF

DECLARATION UNDER 37 CFR §1.132 OF DR. ARTHUR RAINES

RECEIVED

Commissioner of Patents and Trademarks
Washington, D.C. 20231

MAY 29 1996

GROUP 1500

Sir:

I, Arthur Raines, Ph.D., state and declare that:

1. I am a Professor of Pharmacology at Georgetown University in Washington, D.C. My Curriculum Vitae is appended hereto as Exhibit 1.

2. I understand that the examiner of the above-captioned application has maintained a rejection of the claims under 35 USC §102(e), as being anticipated by O'Neill et al., U.S. patent No. 5,268,181 (1993) ("the O'Neill patent"). I also understand that the basis of the rejection is that the O'Neill patent discloses a method of treating hyperlipidemia comprising the administration of a single daily dose of a particular niacin composition, preferably, at, or immediately following, the evening meal, but before bedtime. I further understand that the examiner has taken the position that the administration of niacin in the evening or at night is supported by the parent application of the O'Neill patent (Evanstad et al., U.S. patent No. 5,126,145 (1992) ["the Evanstad patent"]), which teaches the administration of niacin twice daily. In particular, the Evanstad patent states that "[t]ablets can be scored to permit dasy [sic] breakage into smaller doses for titration up to the standard 750 mg. dose given twice daily." Evanstad patent at column 5, lines 58-60.

3. My review of the Evanstad patent revealed that the patent discloses a formulation of a sustained release tablet suitable for use with highly water soluble drugs, which can present formulation problems. The Evanstad patent describes the use of hydroxypropyl methylcellulose and other ingredients to retard the dissolution of water soluble drugs and thus prolong the period of their absorption. Accordingly, the patent is entitled "Controlled release tablet containing water soluble medicament."

4. The Evanstad patent indicates that niacin, which is the water soluble agent used as an example of the invention, could be administered twice a day. See the Evanstad patent at column 5, lines 54-62. According to the patent, the stated purpose of the sustained release is to aid in avoiding side effects (which might occur with a standard tablet dosage form where release usually occurs more rapidly and can lead to headache, dizziness, tingling and flushing). At no point in the patent is the issue of a specified time of administration of niacin mentioned, nor is the issue of diurnal variation in lipid biosynthesis addressed; therefore, the timing of the dose to a particularly appropriate part of the day to enhance efficacy is not a component of the Evanstad patent.

5. On the other hand, my review of the O'Neill patent revealed that the document specifically addresses the issue of administering the niacin at a specified time period based on the variation in lipid biosynthesis which occurs over the 24 hour time period. See the O'Neill patent at column 2 (lines 45-53), column 3 (lines 15-22) and column 10 (lines 34-37). The O'Neill patent calls for the taking of the sustained release dosage form at some time with or after the evening meal or at bedtime. This will presumably allow for medication levels to be optimal at the time of peak synthesis of serum lipids.

6. In summary, the Evanstad patent does not teach or even suggest the O'Neill method of administering niacin at a time of day targeted to coincide with the time at which cholesterol is

Serial No. 08/368,378

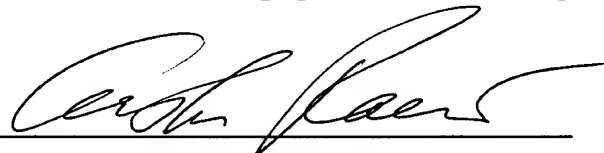
maximally synthesized in the human liver. The once daily, diurnal variation-related dose of niacin described by O'Neill cannot be said to follow from the two dose, diurnal variation-unrelated regimen of Evanstad.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

May 22, 1996

By:



Arthur Raines

LAB NO. 0289731

PAGE 1

90-FLORIDA INC.
6244 S MILITARY TRAIL S-590
MY BEACH, FL 33484

DATE COLLECTED 06/27/90

TIME COLLECTED 0950

AGE 52

SEX F

DATE ENTERED 06/27/90

DATE REPORTED 06/28/90

5:31AM

REPORT STATUS FINAL

06279012378/3680550

* CONFIDENTIAL REPORT *

SA 00

ROUTE W3

STOP 160

MMENTS:

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
BENZYLME PLUS/CBC/UA					
GLUCOSE	101		MG/DL	80 - 125	(1)
SODIUM	140		MEQ/L	135 - 148	
POTASSIUM	4.6		MEQ/L	3.5 - 5.3	
CHLORIDE	106		MEQ/L	95 - 110	
CARBON DIOXIDE CONTENT	24		MEQ/L	24 - 32	
ELECTROLYTE BALANCE	10			0 - 15	
UREA NITROGEN	20		MG/DL	7 - 25	
CREATININE	1.0		MG/DL	0.7 - 1.4	
BUN/CREATININE RATIO	20			8 - 20	
URIC ACID	4.0		MG/DL	2.5 - 7.5	
CALCIUM	10.1		MG/DL	8.5 - 10.5	
PHOSPHORUS, INORGANIC	3.4		MG/DL	2.5 - 4.5	
PROTEIN, TOTAL	6.9		GM/DL	6.0 - 8.0	
ALBUMIN	4.2		GM/DL	3.2 - 5.5	
GLOBULIN	2.7		GM/DL	1.5 - 2.5	
A/G RATIO	1.6			1.1 - 2.2	
CALCIUM, IONIZED	4.5		MG/DL	3.5 - 4.5	
BILIRUBIN, TOTAL	0.3		MG/DL	0.2 - 1.2	
TOTAL	103		U/L	20 - 140	
ASPARTATE AMINOTRANSFERASE					
ASPARTATE TRANSAMINASE					
ALANINE AMINOTRANSFERASE					
CHOLESTEROL, TOTAL			MG/DL	0 - 197	
DESIRABLE ADULT LEVEL FOR CHOLESTEROL IS LESS THAN 200 MG/DL.					
TRIGLYCERIDES	74		MG/DL	20 - 190	
WHITE BLOOD CELLS	4.4		THOUSAND/CU.MM.	3.8 - 10.8	
HEMOGLOBIN (B)	13.9		GM/DL	12.0 - 15.6	
HEMATOCRIT					
MCV	91.4		FEMTOLITERS	80.0 - 100.0	
MCH	30.3				
MCHC	33.2		%	32.0 - 36.0	
PLATELET COUNT	341		THOUSAND/CU.MM.	130 - 400	
NEUTROPHILS	56				
NEUTROPHILS, ABSOLUTE	2.47		THOUSAND/CU.MM.	1.2 - 8.10	

REPORT CONTINUED ON NEXT PAGE

LAB NO. 0702524

PAGE 1

85 FLORIAN INC.
6244 S. MILITARY TRAIL S. 590
MIAMI BEACH, FL 33434

DATE COLLECTED 07/02/90

TIME COLLECTED 0830

AGE 52

SEX F

DATE ENTERED 07/02/90

DATE REPORTED 07/04/90

5:22AM

REPORT STATUS FINAL

0702501399073044770

* CONFIDENTIAL REPORT *

IEA 00

ROUTE W3

STOP 160

IMMUNO: FASTING

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
THYROID PEROXIDASE					
CHOLINERGI					
GLUCOSE	108		MG/DL	80-120	
SODIUM	143		MEQ/L	135-145	
POTASSIUM	4.2		MEQ/L	3.5-5.3	
CHLORIDE	105		MEQ/L	95-110	
CARBON DIOXIDE CONTENT		23 L	MEQ/L	24-32	
ELECTROLYTE BALANCE	15			5-15	
UREA NITROGEN	21		MG/DL	7-25	
CREATININE	0.9		MG/DL	0.7-1.3	
BUN/CREATININE RATIO		23 U		8-20	
URIC ACID	4.3		MG/DL	2.5-7.0	
CALCIUM	9.5		MG/DL	8.5-10.5	
PHOSPHORUS, INORGANIC	3.7		MG/DL	2.5-4.5	
PROTEIN, TOTAL	6.6		GM/DL	6.0-8.5	
ALBUMIN	4.3		GM/DL	3.2-5.2	
GLOBULIN	2.3		GM/DL	1.5-3.0	
A/G RATIO	1.9			1.1-2.2	
CHOLESTEROL, TOTAL	4.3		MG/DL	140-240	
BILIRUBIN, TOTAL	0.3		MG/DL	0.2-1.2	
ALKALINE PHOSPHATASE					
TOTAL	98		U/L	20-140	
LACTATE DEHYDROGENASE	130		U/L	50-250	
ASPARTATE TRANSAMINASE (SGPT)	27		U/L	0-50	
ALANINE AMINOTRANSFERASE (SGOT)	23		U/L	0-50	
AMYLASE, TOTAL			MG/DL	0-170	
DESIRABLE ADULT LEVEL FOR CHOLESTEROL IS LESS THAN 200 MG/DL.					
TRIGLYCERIDES	87		MG/DL	20-170	
IRON, TOTAL	87		MG/DL	40-160	
GRAVIMETRIC TESTS					
NO SPECIMEN RECEIVED					
CHOLESTEROL, HIGH DENSITY Lipoprotein	70		MG/DL		
DESIRABLE LEVELS OF HDL CHOLESTEROL ARE: MALE GREATER THAN 40 FEMALE GREATER THAN 50					
LDL CHOLESTEROL	100 H		MG/DL	LESS THAN 130	

>> REPORT CONTINUED ON NEXT PAGE <<

may 1/9/90

INDICATES TESTING SITE SEE REVERSE SIDE ↑

LAB NO. 2502783

PAGE 1

ES-FLORIDA INC
5244 S MILITARY TRAIL S-590
Y BEACH, FL 33484

DATE COLLECTED 09/07/90
TIME COLLECTED 9:15A
DATE ENTERED 09/07/90 05
DATE REPORTED 09/08/90 9:03AM
REPORT STATUS FINAL

AGE 53

SEX F

* CONFIDENTIAL REPORT **

EA 00 ROUTE W3 STOP 160

MMENTS: NONFASTING

09079012340/652679F

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
CHEMZYME PLUS/CBC/UA					
CHEMZYME					
GLUCOSE	101		MG/DL	80 - 125	MI
SODIUM	140		MEQ/L	135-148	
POTASSIUM	4.4		MEQ/L	3.5-5.3	
CHLORIDE	104		MEQ/L	95-110	
CARBON DIOXIDE CONTENT	24		MEQ/L	24 - 32	
ELECTROLYTE BALANCE	12			5-15	
UREA NITROGEN	18		MG/DL	7-25	
CREATININE	1.0		MG/DL	0.7-1.4	
BUN/CREATININE RATIO	18			8-20	
URIC ACID	6.2		MG/DL	2.5 - 7.5	
CALCIUM	9.4		MG/DL	8.5-10.4	
PHOSPHORUS, INORGANIC	3.7		MG/DL	2.5-4.5	
PROTEIN, TOTAL	6.9		GM/DL	6.0-8.0	
ALBUMIN	4.4		GM/DL	3.2-5.5	
GLOBULIN	2.5		GM/DL	1.5-2.0	
A/G RATIO	1.8			1.1-2.2	
BILIRUBIN, TOTAL	0.4		MG/DL	0.2-1.2	
LACTATE DEHYDROGENASE	144		U/L	0 - 250	
ALT (SGPT)	26		U/L	0 - 55	
200 - 239 MG/DL IS BORDERLINE HIGH FOR 30 YEARS OLD OR GREATER					
IRON, TOTAL	71		MCG/DL	40 - 150	
COMPLETE BLOOD CT & DIFF					
THOUSAND/CU.MM.					
RED BLOOD CELLS	4.95		MILLIONS/CU.MM.	3.90 - 5.20	
HEMATOCRIT	43.9		%	35.0 - 46.0	
MCH	29.6		PICOGRAMS	27.0 - 33.0	
RDW	13.2		UNITS	10.0 - 15.0	
THOUSAND/CU.MM.					
NEUTROPHILS	58		%	40 - 75	
LYMPHOCYTES	32		%	18 - 47	
MONOCYTES	5		%	0 - 10	
EOSINOPHILS	3		%	0 - 6	

SS REPORT CONTINUED ON NEXT PAGE 2A

ACCT. NO.

Best Available Copy

Clinical Laboratories

LAB NO.

DATE COLLECTED 07/05/90

TIME COLLECTED 0830

DATE ENTERED 07/06/90

DATE REPORTED 07/06/90

REPORT STATUS FINAL

070590010107/000-01

PAGE 1

ES-FLORIDA INC
6244 S MILITARY TRAIL S-090
MY BEACH, FL 33434

* CONFIDENTIAL REPORT *

EA 00 ROUTE W3 STOP 100

COMMENTS:

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
HEMZYME PLUS/CBC/UA					
CHEMZYME					MI
GLUCOSE	105		MG/DL	80 - 125	
SODIUM	139		MMOL/L	135 - 145	
POTASSIUM	4.4		MMOL/L	3.5 - 5.3	
CHLORIDE	104		MMOL/L	95 - 110	
CARBON DIOXIDE CONTENT	26		MMOL/L	24 - 32	
ELECTROLYTE BALANCE	9			5 - 15	
UREA NITROGEN	19		MG/DL	7 - 25	
CREATININE	1.0		MG/DL	0.7 - 1.4	
BUN/CREATININE RATIO	19			8 - 20	
URIC ACID	4.2		MG/DL	2.5 - 7.5	
CALCIUM	9.7		MG/DL	8.5 - 10.5	
PHOSPHORUS, INORGANIC	3.7		MG/DL	2.5 - 4.5	
PROTEIN, TOTAL	5.7		GM/DL	5.0 - 8.0	
ALBUMIN	4.3		GM/DL	3.2 - 5.5	
GLOBULIN	2.5		GM/DL	1.5 - 3.8	
A/G RATIO	1.7			1.1 - 2.2	
CALCIUM, IONIZED	4.3		MG/DL	3.8 - 4.8	
BILIRUBIN, TOTAL	0.5		MG/DL	0.2 - 1.2	
ALKALINE PHOSPHATASE, TOTAL	100		U/L	20 - 140	
LACTATE DEHYDROGENASE	139		U/L	0 - 250	
ASPARTATE TRANSAMINASE (SGOT)	23		U/L	0 - 40	
ALANINE AMINOTRANSFERASE (SGPT)	29		U/L	0 - 35	
CHOLESTEROL, TOTAL			MG/DL	0 - 199	
DESIRABLE ADULT LEVEL FOR CHOLESTEROL IS LESS THAN 200 MG/DL.					
TRIGLYCERIDES	147		MG/DL	20 - 150	
IRON, TOTAL	130		MG/DL	40 - 160	
CBC, DIFFERENTIAL					
NO SPECIMEN RECEIVED					
CHOLESTEROL, HIGH DENSITY LIPOPROTEIN			MG/DL		MI
DESIRABLE LEVELS OF HDL CHOLESTEROL ARE MALE GREATER THAN 40 FEMALE GREATER THAN 35					
LDL CHOLESTEROL			MG/DL		
DESIRABLE LEVELS OF LDL CHOLESTEROL ARE LESS THAN 130					
SEE REPORT CONTINUED ON NEXT PAGE <<					

LAB NO.

PAGE

ES-FLORIDA INC
34 S MILITARY TRAIL S-590
DAY BEACH, FL 33484

DATE COLLECTED 07/17/90

TIME COLLECTED 07:30

DATE ENTERED 07/17/90

44

M

DATE REPORTED 07/17/90

REPORT STATUS 07/17/90

514166

FINA

071690141207458111

A CONTINUED ROUTE REPORT STOP

IMENTS: ROUTE M5 140

PAGE TWO

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
CHIMZYME					M1
CHLORIDE	95		MG/DL	70 - 115	
SODIUM	140		MEQ/L	135 - 145	
POTASSIUM	4.0		MEQ/L	3.5 - 5.1	
CHLORIDE	105		MEQ/L	95 - 110	
CARBON DIOXIDE CONTENT	27		MEQ/L	24 - 32	
ELECTROLYTE BALANCE	8			5 - 15	
UREA NITROGEN	13		MG/DL	7 - 28	
CREATININE	1.3		MG/DL	0.7 - 1.4	
BUN/CREATININE RATIO	12			8 - 20	
URIC ACID	6.3		MG/DL	4.0 - 8.5	
CALCIUM	9.8		MG/DL	8.5 - 10.5	
PHOSPHORUS, INORGANIC	3.3		MG/DL	2.5 - 4.5	
PROTEIN, TOTAL	6.4		GM/DL	6.0 - 8.5	
ALBUMIN	4.2		GM/DL	3.2 - 5.5	
GLOBULIN	2.2		GM/DL	1.5 - 3.0	
A/G RATIO	1.9			1.1 - 2.2	
CALCIUM, IONIZED	4.4		MG/DL	3.8 - 4.8	
BILIRUBIN, TOTAL	0.4		MG/DL	0.2 - 1.2	
ALKALINE PHOSPHATASE					
TOTAL	54		U/L	20 - 140	
LACTATE DEHYDROGENASE	132		U/L	0 - 250	
ASPARTATE TRANSAMINASE (SGOT)	17		U/L	0 - 50	
ALANINE AMINOTRANSFERASE (SGPT)	18		U/L	0 - 50	
CHOLESTEROL			MG/DL	0 - 177	
DESIRABLE ADULT LEVEL FOR CHOLESTEROL IS LESS THAN 200 MG/DL					
TRIGLYCERIDES	300		MG/DL	20 - 150	
IRON, TOTAL	83		MCG/DL	40 - 150	
BC, PLATELET CT & DIFF					M1
WHITE BLOOD CELLS	4.5		THOUSAND/CC, MM	3.8 - 10.8	
RED BLOOD CELLS	4.87		MILLIONS/CC, MM	4.40 - 5.80	
HEMOGLOBIN (G)	15.2		GM/DL	13.5 - 17.2	
HEMATOCRIT	47.6		%	41.0 - 50.0	
MCV	97.9		FEMTO LITERS	80.0 - 100.0	
MCH	31.1		PECOGRAMS	27.0 - 32.0	
MCHC	34.7		%	32.0 - 36.0	
RDW	12.5		UNITS	10.0 - 13.0	
PLATELET COUNT	212		THOUSAND/CC, MM	130 - 400	
NEUTROPHILS	58		%	40 - 75	
NEUTROPHILS, ABSOLUTE	3.71		THOUSAND/CC, MM	1.52 - 8.10	

REPORT CONTINUED ON NEXT PAGE <<

LAB NO. 0289719

PAGE 1

MS-FLORIDA INC
 4 S MILITARY TRAIL S-890
 DAY BEACH, FL 33484

DATE COLLECTED 07/19/90
 TIME COLLECTED 8:30A AGE 44 SEX M
 DATE ENTERED 07/19/90
 DATE REPORTED 07/22/90 5:37AM
 REPORT STATUS FINAL

* CONFIDENTIAL REPORT **

SEA 00 ROUTE 03 STOP 160

REMARKS:

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
LDL DISEASE PROFILE CHOLESTEROL, TOTAL	290 H		MG/DL	0 - 199	MJ
DESIRABLE ADULT LEVEL FOR CHOLESTEROL IS LESS THAN 200 MG/DL.					
TRIGLYCERIDES	269 H		MG/DL	20-160	MJ
LIPOPROTEIN PHENOTYPE INTERPRETATION					MI
INTERPRETATION: TYPE IV PHENOTYPE.					
PATTERN SHOWS A DENSE PRE-BETA LIPOPROTEIN FRACTION, NORMAL BETA- AND ALPHA FRACTIONS AND NO CHYLOMICRONS. THIS PATTERN, ASSOCIATED WITH NORMAL OR SLIGHTLY ELEVATED CHOLESTEROL, ELEVATED TRIGLYCERIDES AND EITHER CLEAR OR TURBID SERUM, IS CONSISTENT WITH THE ABOVE.					
NOTE: PROPER INTERPRETATION OF LIPOPROTEIN PATTERNS BASED ON THE FREDRICKSON CLASSIFICATION REQUIRES FASTING OF AN AMERICAN INDIVIDUAL FOR AT LEAST 7 DAYS AND NO FOOD INGESTION 12 - 14 HOURS BEFORE THE SPECIMEN IS COLLECTED. ABNORMAL RESULTS ARE FREQUENTLY CAUSED BY UNDERLYING CONDITIONS RATHER THAN A GENETIC PREDISPOSITION.					
APPEARANCE	CLEAR				
HALE SENDUPTA, M.D., PATHOLOGIST					
LDL CHOLESTEROL			MG/DL	0 - 199	MJ
DESIRABLE ADULT LEVEL FOR CHOLESTEROL IS LESS THAN 200 MG/DL.					
LDL CHOLESTEROL	269 H		MG/DL	20-160	MJ
CHOLESTEROL, HIGH DENSITY LIPOPROTEIN	34 L		MG/DL		MI
DESIRABLE LEVELS OF HDL CHOLESTEROL ARE MALE GREATER THAN 45 FEMALE GREATER THAN 55					
LDL CHOLESTEROL	202 H		MG/DL	LESS THAN 130	
>> REPORT CONTINUED ON NEXT PAGE <<					

LAB NO. 3502511

PAGE 1

ES-FLORIDA INC
6244 S MILITARY TRAIL S-590
EY BEACH, FL 33484

09/28/90
TIME COLLECTED 850AM
DATE ENTERED 09/28/90
DATE REPORTED 10/01/90 5:36AM
REPORT STATUS FINAL

AGE 44 SEX M

* CONFIDENTIAL REPORT **

IEA 01 ROUTE 03 STOP 100

IMMUNTS: "FASTING SPECIMEN"

092070126197/14851P

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
CHEMZYME PLUS/CPC/LA					
CHEMZYME					
GLUCOSE	103		MG/DL	70 - 115	MI
SODIUM	142		MEQ/L	135 - 148	
POTASSIUM	3.9		MEQ/L	3.5-5.3	
CHLORIDE	109		MEQ/L	95-110	
CARBON DIOXIDE CONTENT	25		MEQ/L	24 - 32	
ELECTROLYTE BALANCE	0			0-15	
UREA NITROGEN	18		MG/DL	7-25	
CREATININE	1.2		MG/DL	0.7-1.4	
BUN/CREATININE RATIO	15			8-20	
URIC ACID	6.2		MG/DL	4.0-8.5	
CALCIUM	9.3		MG/DL	8.5-10.6	
PHOSPHORUS, INORGANIC	2.6		MG/DL	2.5-4.5	
PROTEIN, TOTAL	6.4		GM/DL	6.0-8.5	
ALBUMIN	4.0		GM/DL	3.2-5.5	
GLOBULIN	2.4		GM/DL	1.5-3.8	
A/G RATIO	1.7			1.1-2.2	
CALCIUM, IONIZED	4.3		MG/DL	3.8-4.8	
BILIRUBIN, TOTAL	0.7		MG/DL	0.2-1.2	
ALK PHOS, TOTAL	51		U/L	20 - 140	
LACTATE DEHYDROGENASE	156		U/L	0 - 250	
AST (SGOT)	21		U/L	0-50	
ALT (SGPT)	30		U/L	0 - 55	
			MG/DL	LESS THAN 200	
200 - 259 MG/DL IS BORDERLINE HIGH FOR 20 YEARS OLD OR GREATER					
TRIGLYCERIDES		222 H	MG/DL	20-160	
IRON, TOTAL	128		MCG/DL	40 - 150	
COMPLETE BLOOD CT & DIFF					
WHITE BLOOD CELLS	5.8		THOUSAND/CU.MM.	3.8 - 10.8	MI
RED BLOOD CELLS	4.65		MILLIONS/CU.MM.	4.40 - 5.80	
HEMOGLOBIN (B)	14.2		GM/DL	13.8 - 17.2	
HEMATOCRIT	41.8		%	41.0 - 50.0	
MCV	90.0		FEMTOLITERS	80.0 - 100.0	
MCH	30.6		PICOGRAMS	27.0 - 33.0	
MCHC	34.1		%	32.0 - 36.0	
RDW	10.4		UNITS	10.0 - 15.0	
PLATELET COUNT	154		THOUSAND/CU.MM.	130 - 400	
NEUTROPHILS	58		%	40 - 75	
NEUTROPHILS, ABSOLUTE	3.35		THOUSAND/CU.MM.	1.52 - 8.10	
LYMPHOCYTES	32		%	18 - 47	
LYMPHOCYTES, ABSOLUTE	1.84		THOUSAND/CU.MM.	0.68 - 5.07	
MONOCYTES	8		%	0 - 10	
MONOCYTES, ABSOLUTE	0.33		THOUSAND/CU.MM.	0.10 - 1.08	
EOSINOPHILS	3		%	0 - 6	

>> REPORT CONTINUED ON NEXT PAGE <<

PES-FLORIDA INC
14244 S MILITARY TRAIL S-590
1 RAY BEACH, FL 33484

DATE COLLECTED 08/30/90

TIME COLLECTED 0800

AGE 56 SEX F

DATE ENTERED 08/30/90

DATE REPORTED 08/31/90

5:27AM

REPORT STATUS FINAL

08309011713/620951P

** CONFIDENTIAL REPORT **

EA 00

ROUTE W3 STOP 160

MMENTS:

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
CHEMZYME PLUS/CBC/UA					
CHEMZYME					
GLUCOSE	89		MG/DL	80 - 125	MI
SODIUM	142		MEQ/L	135-148	
POTASSIUM	4.3		MEQ/L	3.5-5.3	
CHLORIDE	104		MEQ/L	95-110	
CARBON DIOXIDE CONTENT	28		MEQ/L	24 - 32	
ELECTROLYTE BALANCE	10			5-15	
UREA NITROGEN	17		MG/DL	7-25	
CREATININE	1.2		MG/DL	0.7-1.4	
BUN/CREATININE RATIO	14			8-20	
URIC ACID	3.4		MG/DL	2.5 - 7.5	
CALCIUM	9.6		MG/DL	8.5-10.6	
PHOSPHORUS, INORGANIC	3.9		MG/DL	2.5-4.5	
PROTEIN, TOTAL	6.9		GM/DL	6.0-8.5	
ALBUMIN	3.9		GM/DL	3.2-5.5	
GLOBULIN	3.0		GM/DL	1.5-3.8	
A/G RATIO	1.3			1.1-2.2	
CALCIUM, IONIZED	4.3		MG/DL	3.8-4.8	
BILIRUBIN, TOTAL	0.5		MG/DL	0.2-1.2	
ALKALINE PHOSPHATASE,					
TOTAL	77		U/L	20 - 140	
LACTATE DEHYDROGENASE	126		U/L	0 - 250	
ASPARTATE TRANSAMINASE (SGOT)	22		U/L	0-50	
ALANINE AMINOTRANSFERASE (SGPT)	14		U/L	0 - 55	
CHOLESTEROL, TOTAL			MG/DL	0 - 199	
DESIRABLE ADULT LEVEL FOR CHOLESTEROL IS LESS THAN 200 MG/DL.					
TRIGLYCERIDES		239 H	MG/DL	20-190	
IRON, TOTAL	66		MG/DL	40 - 150	
CBC, PLATELET COUNT DIFF					
WHITE BLOOD CELLS		3.7 L		THOUSAND/CU.MM. 3.8 - 10.8	MI
RED BLOOD CELLS	4.06			MILLIONS/CU.MM. 3.90 - 5.20	
HEMOGLOBIN (B)	12.3		GM/DL	12.0 - 15.6	
HEMATOCRIT	36.5		%	35.0 - 46.0	
MCV	89.9		FEMTOLITERS	80.0 - 100.0	
MCH	30.3		PICOGRAMS	27.0 - 33.0	
MCHC	33.8		%	32.0 - 36.0	
RDW	10.8		UNITS	10.0 - 15.0	
PLATELET COUNT	141		THOUSAND/CU.MM.	130 - 400	
NEUTROPHILS	50		%	40 - 75	
NEUTROPHILS, ABSOLUTE	1.88		THOUSAND/CU.MM.	1.52 - 8.10	

>> REPORT CONTINUED ON NEXT PAGE <<

ES-FLORIDA INC
6244 S MILITARY TRAIL S-590
FAY BEACH, FL 33484

LAB NO. 2502756

PAGE 1

DATE COLLECTED 09/04/90

TIME COLLECTED 0900

AGE 56 SEX F

DATE ENTERED 09/04/90

DATE REPORTED 09/05/90

5:19AM

REPORT STATUS FINAL

09049011342/632587P

* CONFIDENTIAL REPORT **

EA 00 ROUTE W3 STOP 100

MMENTS: *FASTING SPECIMEN*

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
A.R.E. PANEL #2 CHOLESTEROL, TOTAL			MG/DL	0 - 199	MI
DESIRABLE ADULT LEVEL FOR CHOLESTEROL IS LESS THAN 200 MG/DL.					
TRIGLYCERIDES	234 H		MG/DL	20-190	MI
CHOLESTEROL, HIGH DENSITY LIPOPROTEIN	35 L		MG/DL		MI
DESIRABLE LEVELS OF HDL CHOLESTEROL ARE: MALE GREATER THAN 45 FEMALE GREATER THAN 55					
LDL CHOLESTEROL	165 H		MG/DL	LESS THAN 130	
CHOLESTEROL/HDL RATIO	7.06				

CORONARY HEART DISEASE RISK TABLE

RELATIVE RISK	T/HDL CHOL RATIO
MEN 0.5 AVERAGE	3.43
AVERAGE	4.97
2 X AVERAGE	9.55
3 X AVERAGE	23.39
WOMEN 0.5 AVERAGE	3.27
AVERAGE	4.44
2 X AVERAGE	7.05
3 X AVERAGE	11.04

>> END OF REPORT <<

Craig
9/5/90

LAB NO. 2502782

PAGE 1

IS-FLORIDA INC
6244 S MILITARY TRAIL S-590
MY BEACH, FL 33484

DATE COLLECTED 09/07/90

TIME COLLECTED 0800

AGE 56 SEX F

DATE ENTERED 09/07/90

DATE REPORTED 09/08/90

9:03AM

REPORT STATUS FINAL

09079012100/691675P

CONFIDENTIAL REPORT **

SA 00 ROUTE W3 STOP 160

MENTS:

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
A.P.E. PANEL #2					
CHOLESTEROL, TOTAL			MG/DL	LESS THAN 200 MI	
200 - 239 MG/DL IS BORDERLINE HIGH FOR 20 YEARS OLD OR GREATER					
TRIGLYCERIDES	243 H		MG/DL	20-190	MI
					MI
CHOLESTEROL, HIGH DENSITY LIPOPROTEIN	35 L		MG/DL		
DESIRABLE LEVELS OF HDL CHOLESTEROL ARE: MALE GREATER THAN 45					
FEMALE GREATER THAN 55					
LDL CHOLESTEROL	186 H		MG/DL	LESS THAN 130	
CHOLESTEROL/HDL RATIO	7.71				

CORONARY HEART DISEASE RISK TABLE

	RELATIVE RISK	T/HDL CHOL RATIO
MEN	0.5 AVERAGE	3.43
	AVERAGE	4.97
	2 X AVERAGE	9.55
	3 X AVERAGE	23.39
WOMEN	0.5 AVERAGE	3.27
	AVERAGE	4.44
	2 X AVERAGE	7.05
	3 X AVERAGE	11.04

>> END OF REPORT <<

ES-FLORIDA INC
44 S MILITARY TRAIL S-590
DAY BEACH, FL 33484

11/12/90
TIME COLLECTED 830 AGE 47 SEX F
DATE ENTERED 11/12/90
DATE REPORTED 11/13/90 5:16AM
REPORT STATUS FINAL
11129012576/039506V

* CONFIDENTIAL REPORT **

A 00 ROUTE W3 STOP 160
MENTS: "FASTING SPECIMEN"

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
CHEMZYME PLUS/CBC/UA					
CHEMZYME					MI
GLUCOSE	103		MG/DL	70 - 115	
SODIUM	144		MEQ/L	135 - 148	
POTASSIUM	3.8		MEQ/L	3.5 - 5.3	
CHLORIDE	104		MEQ/L	95 - 110	
CARBON DIOXIDE CONTENT	28		MEQ/L	24 - 32	
ELECTROLYTE BALANCE	12			5-15	
UREA NITROGEN	19		MG/DL	7 - 25	
CREATININE	1.2		MG/DL	0.7 - 1.4	
BUN/CREATININE RATIO	16			8-20	
URIC ACID	4.2		MG/DL	2.5 - 7.5	
CALCIUM	9.3		MG/DL	8.5 - 10.6	
PHOSPHORUS, INORGANIC	3.5		MG/DL	2.5-4.5	
PROTEIN, TOTAL	6.7		GM/DL	6.0-8.5	
ALBUMIN	3.8		GM/DL	3.2-5.5	
GLOBULIN, TOTAL	2.9		GM/DL	1.5-3.8	
A/G RATIO	1.3			1.1-2.2	
CALCIUM, IONIZED	4.2		MG/DL	3.8-4.8	
BILIRUBIN, TOTAL	0.7		MG/DL	0.2 - 1.2	
ALK PHOS, TOTAL	81		U/L	20 - 140	
LACTATE DEHYDROGENASE	147		U/L	0 - 250	
AST (SGOT)		52 H <i>NCS</i>	U/L	0-50	
ALT (SGPT)	46		U/L	0 - 55	
			MG/DL	LESS THAN 200	
200 - 239 MG/DL IS BORDERLINE HIGH FOR 20 YEARS OLD OR GREATER					
TRIGLYCERIDES		170 H	MG/DL	20-160	
IRON, TOTAL	68		MCG/DL	40 - 150	
COMPLETE BLOOD CT & DIFF					
WHITE BLOOD CELLS					MI
RED BLOOD CELLS	4.40		MILLIONS/CU.MM.	3.90 - 5.20	
HEMOGLOBIN (B)	13.2		GM/DL	12.0 - 15.6	
HEMATOCRIT	39.2		%	35.0 - 46.0	
MCV	89.0		FEMTOLITERS	80.0 - 100.0	
MCH	30.0		PICOGRAMS	27.0 - 33.0	
MCHC	33.7		%	32.0 - 36.0	
RDW	12.5		UNITS	10.0 - 15.0	
PLATELET COUNT	142		THOUSAND/CU.MM.	130 - 400	
NEUTROPHILS	53		%	40 - 75	
NEUTROPHILS, ABSOLUTE	2.78		THOUSAND/CU.MM.	1.52 - 8.10	
LYMPHOCYTES	37		%	18 - 47	
LYMPHOCYTES, ABSOLUTE	1.88		THOUSAND/CU.MM.	0.68 - 5.07	
MONOCYTES	6		%	0 - 10	
MONOCYTES, ABSOLUTE	0.28		THOUSAND/CU.MM.	0.10 - 1.08	
EOSINOPHILS	3		%	0 - 6	

>> REPORT CONTINUED ON NEXT PAGE <<

PES-FLORIDA INC
16244 S MILITARY TRAIL S-590
DEER BEACH, FL 33484

** CONFIDENTIAL REPORT **

AREA 00 ROUTE W3 STOP 160
COMMENTS: FASTING

LAB NO. 2502801

PAGE 1

DATE COLLECTED 09/19/90

TIME COLLECTED 0830

AGE 47

SEX M

DATE ENTERED 09/19/90

DATE REPORTED 09/20/90

7:44AM

REPORT STATUS FINAL

09199011339/702808P

TEST	RESULT	OUT OF RANGE (OR INTERPRETATION)	UNITS	REFERENCE RANGE	SC
CHEMZYME PLUS/CBC/UA					
CHEMZYME					
GLUCOSE	97		MG/DL	70 - 115	MI
SODIUM	139		MEQ/L	135-148	
POTASSIUM	4.2		MEQ/L	3.5-5.3	
CHLORIDE	103		MEQ/L	95-110	
CARBON DIOXIDE CONTENT	27		MEQ/L	24 - 32	
ELECTROLYTE BALANCE	9			5-15	
UREA NITROGEN	13		MG/DL	7-25	
CREATININE	1.2		MG/DL	0.7-1.4	
BUN/CREATININE RATIO	11			8-20	
URIC ACID	6.6		MG/DL	4.0-8.5	
CALCIUM	8.9		MG/DL	8.5-10.6	
PHOSPHORUS, INORGANIC	2.8		MG/DL	2.5-4.5	
PROTEIN, TOTAL	6.7		GM/DL	6.0-8.5	
ALBUMIN	4.0		GM/DL	3.2-5.5	
GLOBULIN	2.7		GM/DL	1.5-3.8	
A/G RATIO	1.5			1.1-2.2	
CALCIUM, IONIZED	4.0		MG/DL	3.8-4.8	
BILIRUBIN, TOTAL	0.6		MG/DL	0.2-1.2	
ALK PHOS, TOTAL	55		U/L	20 - 140	
LACTATE DEHYDROGENASE	125		U/L	0 - 250	
AST (SGOT)	21		U/L	0-50	
ALT (SGPT)	22		U/L	0 - 55	
			MG/DL	LESS THAN 200	
200 - 239 MG/DL IS BORDERLINE HIGH FOR 20 YEARS OLD OR GREATER					
TRIGLYCERIDES	162 H		MG/DL	20-160	
IRON, TOTAL	102		MCG/DL	40 - 150	

COMPLETE BLOOD CT & DIFF

WHITE BLOOD CELLS	5.0		THOUSAND/CU.MM.	3.8 - 10.8	MI
RED BLOOD CELLS	4.49		MILLIONS/CU.MM.	4.40 - 5.80	
HEMOGLOBIN (D)	13.8		GM/DL	13.8 - 17.2	
HEMATOCRIT	40.1 L		%	41.0 - 50.0	
MCV	89.3		FEMTOLITERS	80.0 - 100.0	
MCH	30.6		PICOGRAMS	27.0 - 33.0	
MCHC	34.3		%	32.0 - 36.0	
RDW	11.8		UNITS	10.0 - 15.0	
PLATELET COUNT	175		THOUSAND/CU.MM.	130 - 400	
NEUTROPHILS	51		%	40 - 75	
NEUTROPHILS, ABSOLUTE	2.34		THOUSAND/CU.MM.	1.52 - 8.10	
LYMPHOCYTES	39		%	18 - 47	
LYMPHOCYTES, ABSOLUTE	1.93		THOUSAND/CU.MM.	0.68 - 5.07	
MONOCYTES	5		%	0 - 10	
MONOCYTES, ABSOLUTE	0.31		THOUSAND/CU.MM.	0.10 - 1.08	
EOSINOPHILS	3		%	0 - 6	

>> REPORT CONTINUED ON NEXT PAGE <<

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:**

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.